

Personal benefit, helping others motivate clinical trial participants

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Most HIV-infected individuals participating in a clinical trial hope to benefit personally from the research but also understand they are contributing to society, according to a report in the June 23 issue of *Archives of Internal Medicine*, one of the JAMA/Archives journals.

Although there is a growing body of data explaining why individuals enroll in clinical trials, little research has been conducted regarding their motivation for ongoing participation, according to background information in the article. "Why do patient participants, especially those randomized to a control group, continue to accept the added risks and burdens, e.g., additional clinic visits and extra research procedures, that clinical research places on them?" the authors write. "Answering this question is especially important given the view that clinical research inappropriately exploits patient participants by exposing them to added risks and burdens for the benefit of others."

David Wendler, Ph.D., and colleagues at the Department of Bioethics, National Institutes of Health Clinical Center, reported group results of a survey of participants in the Evaluation of Subcutaneous Proleukin (Interleukin-2) in a Randomized International Trial (ESPRIT) study. ESPRIT is a phase 3 trial comparing antiretroviral medications alone to antiretroviral medications plus interleukin 2 (IL-2), a protein associated with the immune system. HIV-infected patients from Argentina, Brazil and Thailand who had been enrolled in the study for at least six months responded to questions regarding their motivations and experiences.

Of the 582 participants who responded to the follow-up survey, 292 were in the treatment group receiving IL-2 and 290 were in the group receiving antiretroviral medication alone. Participants were asked to choose from a list of 12 reasons why they continued to participate in the trial. "More than 80 percent indicated that the opportunity to obtain medical or personal benefit and the opportunity to help others were very important reasons for continuing to participate," the authors write. "Also, 90 percent believed they were making an important contribution to society, and 84 percent expressed pride in helping to advance scientific knowledge."

The findings suggest that patients can have multiple reasons for continuing to participate in clinical research. "Most importantly, the fact that respondents were motivated to obtain treatment for a life-threatening illness did not preclude them from being motivated to help others through their participation in the ESPRIT study as well," the authors conclude.

"These findings reveal that it is possible to conduct clinical research in developing countries without exploiting patient participants' failure to understand that they are participating in research and without exploiting their need for medical treatment to get them to contribute to goals that they do not endorse."

Source: JAMA and Archives Journals

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